

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 05/19/2016

Reviewed on 05/19/2016

1 Identification

- **Product Identifier**
- **Trade name: Aivlosin® 0.425% (Tylvalosin Type B Medicated Feed)**
- **Relevant identified uses of the substance or mixture and uses advised against:**
- **Product Description**
Type B Medicated Article (Premix) -For use in the manufacture of medicated animal feeds.
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**
Pharmgate
14040 Industrial Rd., Omaha, NE 68144
Phone: (402) 330-6000
Fax: (402) 330-6004
- **Emergency telephone number:** (800) 832-8303

2 Hazard(s) Identification

- **Classification of the substance or mixture:**
Combustible Dust May form combustible dust concentrations in air.
- **Label elements:**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms:** Non-Regulated Material
- **Signal word:** Warning
- **Hazard statements:**
May form combustible dust concentrations in air.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**

 - Health = 0
 - Fire = 1
 - Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0
- **Hazard(s) not otherwise classified (HNOC):** None known

3 Composition/Information on Ingredients

- **Non-hazardous components:**
- 63409-12-1 | Tylvalosin (free base)
- 63428-13-7 | Tylvalosin (tartrate)
- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with non-hazardous additions.

- **Dangerous Components:**

CAS: 471-34-1	Calcium Carbonate
RTECS: EV 9580000	
CAS: 8042-47-5	Mineral Oil

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· **Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4 First-Aid Measures

· **Description of first aid measures:**

· **General information:** No special measures required.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Wash with soap and water.

· **After eye contact:**

Rinse opened eye for several minutes under running water.

If eye irritation occurs, consult a doctor.

· **After swallowing:** Treat symptomatically; induction of vomiting may be needed.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed:** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed:**

Notes to Physician: Treat symptomatically.

5 Fire-Fighting Measures

· **Extinguishing media:**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards arising from the substance or mixture:**

The creation of a dust cloud of organic material of any origin may form an explosive mixture with air.

· **Advice for firefighters:**

· **Protective equipment:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures:** Avoid formation of dust.

· **Environmental precautions:** Do not allow to enter sewers/surface or ground water.

· **Methods and material for containment and cleaning up:**

Avoid generating airborne dust. Collect spilled material by a method that controls dust generation. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly.

· **Reference to other sections:**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

· **Handling**

· **Precautions for safe handling:**

Keep away from sources of ignition.

Avoid breathing dust.

· **Information about protection against explosions and fires:**

Dust can combine with air to form an explosive mixture.

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- **Conditions for safe storage, including any incompatibilities:**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool, dry place away from sparks and flame.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store at of below 25°C (77°F)
- **Specific end use(s):** No further relevant information available.

8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**

· **Components with occupational exposure limits:**

471-34-1 Calcium Carbonate

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	TLV withdrawn

8042-47-5 Mineral Oil

ACGIH TLV	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³
OSHA PEL	Long-term value: 5 mg/m ³

- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limit(s) outlined in the SDS. Where acceptable concentrations cannot be maintained by general mechanical ventilation, local exhaust ventilation is recommended.
- **Personal protective equipment:**
- **General protective and hygienic measures:** No special measures required.
- **Breathing equipment:**



Dust mask

- **Protection of hands:**



Protective gloves

- **Material of gloves:** Latex or Polyethylene
- **Penetration time of glove material:**
The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

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Trade name: Aivlosin® 0.425% (Tylvalosin Type B Medicated Feed)**· Eye protection:**

Tightly sealed goggles

· Body protection:

Protective work clothing

*** 9 Physical and Chemical Properties****· Information on basic physical and chemical properties****· General Information****· Appearance:**

Form: Powder
Color: Off White to Light Brown

· Odor: Not determined**· Odor threshold:** Not determined.**· pH-value:** Not applicable.**· Change in condition****Melting point/Melting range:** Not determined.**Boiling point/Boiling range:** Not determined.**· Flash point:** None**· Flammability (solid, gaseous):** Not determined.**· Ignition temperature:** Not determined.**· Decomposition temperature:** Not determined.**· Auto igniting:** Product is not self-igniting.**· Danger of explosion:** Product does not present an explosion hazard.**· Explosion limits:****Lower:** Not determined.**Upper:** Not determined.**· Vapor pressure:** Not determined.**· Density:** Not determined.**· Relative density:** Not determined.**· Vapor density:** Not applicable.**· Evaporation rate:** Not applicable.**· Solubility in / Miscibility with:****Water @ 25 °C (77 °F):** 948 g/l (API)**· Partition coefficient (n-octanol/water):** 3.82 log POW**· Viscosity:****Dynamic:** Not applicable.**Kinematic:** Not applicable.

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- **Other information:** No further relevant information available.

*** 10 Stability and Reactivity**

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**
Carbon monoxide, carbon dioxide and other toxic vapors. Prolonged storage above 77°F should be avoided.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
Keep away from heat, spark, flames and all other sources of ignition. Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects:**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

471-34-1 Calcium Carbonate

Oral LD50 6450 mg/kg (rat)

8042-47-5 Mineral Oil

Oral LD50 >5000 mg/kg (rat)

- **Primary irritant effect:**
- **On the skin:** May be irritating.
- **On the eye:** May be irritating.
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories:**

- **IARC (International Agency for Research on Cancer):**

None of the ingredients are listed.

- **NTP (National Toxicology Program):**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

*** 12 Ecological Information**

- **Toxicity:**
- **Aquatic toxicity:**
Toxicity to Fish: LC₅₀>100 mg tylvalosin/L (rainbow trout)
Toxicity to Daphnids: 48 Hr EC₅₀=617 mg/tylvalosin/L
Toxicity to Plants: LC₅₀>1090 mg tylvalosin/kg soil
- **Persistence and degradability:** DT₅₀ (soil half life) <20 days
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** Low

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- **Mobility in soil:** Poor, Tylvalosin has a very strong affinity for soil.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

13 Disposal Considerations

- **Waste treatment methods:**
- **Recommendation:**
Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport Information

- **UN-Number:**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

Section 355 (extremely hazardous substances):	None of the ingredients are listed.
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Section 313 (Specific toxic chemical listings):	None of the ingredients are listed.
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TSCA (Toxic Substances Control Act):	
471-34-1	Calcium Carbonate
8042-47-5	Mineral Oil

California Proposition 65:	
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Chemicals known to cause cancer:	None of the ingredients are listed.
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· Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed.
· Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.
· Chemicals known to cause developmental toxicity:
None of the ingredients are listed.
· New Jersey Right-to-Know List:
None of the ingredients are listed.
· New Jersey Special Hazardous Substance List:
None of the ingredients are listed.
· Pennsylvania Right-to-Know List:
None of the ingredients are listed.
· Pennsylvania Special Hazardous Substance List:
None of the ingredients are listed.
· Carcinogenic categories:
· EPA (Environmental Protection Agency):
None of the ingredients are listed.
· TLV (Threshold Limit Value established by ACGIH):
None of the ingredients are listed.
· NIOSH-Ca (National Institute for Occupational Safety and Health):
None of the ingredients are listed.
· GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).
· Hazard pictograms: Non-Regulated Material
· Signal word: Warning
· Hazard statements:
May form combustible dust concentrations in air.
· National regulations:
The product is subject to be classified according with the latest version of the regulations on hazardous substances.
· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of preparation / last revision:** 05/19/2016 / 4

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
 ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 IMDG: International Maritime Code for Dangerous Goods
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 ACGIH: American Conference of Governmental Industrial Hygienists
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

BEI: Biological Exposure Limit

· *** Data compared to the previous version altered.**

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